DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 2, 2016

Biomet Manufacturing Corporation
Ms. Patricia S. Beres
Senior Regulatory Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

Re: K072804
Trade/Device Name: Comprehensive® RS Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: September 28, 2007
Received: October 1, 2007

Dear Ms. Beres:

This letter corrects our substantially equivalent letter of December 12, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072804

Device Name: Comprehensive® RS Shoulder System

Indications For Use:
The Comprehensive® RS Shoulder System is indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

A cemented humeral stem must be used.

The MacroBond®/HA RS Cleats are indicated only for uncemented biological fixation applications. The GT Baseplate components are intended for cementless application with the addition of screw fixation.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072804

K072804 (pg 1 of 2)

BIOMET
ORTHOPEDICS, INC.

510(k) Summary

Preparation Date: December 3, 2007

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

DEC 1 2 2007

Proprietary Name: Comprehensive® RS Shoulder System

Common Name: Shoulder replacement components

Classification Name:

- Shoulder joint, metal/polymer, semi-constrained, cemented prosthesis (21 C.F.R. 888.3660) KWS

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- Delta Shoulder and CTA™ Humeral Cups (DePuy) K021478, K050315
- Aequalis® Reversed Shoulder Prosthesis (Tornier) K030941, K041873
- Encore reverse Shoulder Prosthesis (Encore) K041066, K051075
- Zimmer Trabecular Metal™ Reverse Shoulder System K052906
- Bio-Modular® Shoulder System (Biomet) K992119, K030710, K043100

Device Description: The Comprehensive® RS Shoulder System is intended for total shoulder replacement in a reverse shoulder.

Intended Use:
The Comprehensive® RS Shoulder System is indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

A cemented humeral stem must be used.

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

The MacroBond®/HA RS Cleats are indicated only for uncemented biological fixation applications. The GT Baseplate components are intended for cementless application with the addition of screw fixation.

Summary of Technologies: The Comprehensive® RS Shoulder System have similar technologies as the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

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Aequalis is a trademark of Tornier S.A. Corporation
Trabecular Metal are trademarks of Zimmer Trabecular Metal Technology, Inc